flexible region comprising a continuous helical cut formed along a length portion of said body, a coating of adhesive disposed over an outer surface of said body along said length portion, and a heat-shrunk sleeve disposed over said length portion with a close diametric fit, with said adhesive bonding said sleeve to said outer surface of said body along said length portion, said flexible region conforming to said bend while transmitting torque to rotate said cutting configuration when said proximal end of said inner tubular member is rotated in forward and reverse rotational directions, said sleeve bonded to said body providing resistance to wind-up and unwinding of said length portion when transmitting torque." An angled tissue cutting instrument having an elongate flexible inner tubular member with a flexible region as recited in claim 1 is not obvious from Krause et al '350 in view of Krause et al '922, Cesarini et al and either Whayne, Stephan et al or Hinohara et al.

Krause et al '350 does not disclose or suggest the inner tube 14 as having a continuous helical cut, a coating of adhesive, or a heat-shrunk sleeve, much less a sleeve bonded to the inner tube 14 to provide resistance to wind-up and unwinding of a helically cut length portion when transmitting torque in forward and reverse rotational directions. Krause et al '350 discloses the inner tube 14 as having a flexible region 16 formed by circumferential, but discontinuous, slots 60, 62 in the inner tube. It is essential to operation of the instrument disclosed by Krause et al '350 that the slots 60,62 are circumferentially offset with respect to one another, that a pair of opposing tabs 68 of circumferential extent remain between opposing slots 60, and that a pair of opposing tabs 69 of circumferential extent remain between opposing slots 62, thusly providing a series of rings 70 of material interconnected by pairs of tabs 68, 69 along

the length of the flexible region 16. The interconnected rings 70 form a series of essentially H-shaped leaf springs 72 along the length of flexible region 16, and "it is this symmetrical arrangement of interconnected, integrally formed leaf springs 72 that provides region 16 with both uniform flexibility and torsional stiffness" (column 5, lines 58-62). Regardless of whether the slots 60,62 are perpendicular to the longitudinal axis 64 of the inner tube 14 or at an angle to the longitudinal axis 64, the slots 60,62 do not constitute a continuous cut formed along the length of the flexible region 16 of the inner tube 14. As noted, the essence of Krause et al '350 is that the slots 60,62 are not continuous, but rather are separated by tabs 68,69. Moreover, the slots 60,62 are deliberately formed with a relatively substantial width, which is entirely different from a simple helical cut.

The explicit teachings of Krause et al '350 clearly differentiate the flexible region 16 from one that comprises a continuous helical cut which involves wind-up, tightening or preloading before transmitting torque to the cutting implement as well as unwinding when transmitting torque. In particular, Krause et al '350 discloses that the flexible region need not be tightened or preloaded when torque is applied to the proximal end of the inner tube, before passing such torque to the cutting implement at the distal end of the inner tube, such that torque is transmitted to the cutting implement substantially immediately (column 2, lines 16-20; column 7, lines 31-35); that the flexible region does not include a relaxing (i.e. unwinding) and hence expanding helical arrangement (column 2, lines 19-20); that the tabs are necessary to transmit torque (column 5, lines 36-40); that the flexible region has a high degree of torsional stiffness (column 7, lines 29-31); and that the flexible region does not expand in diameter by any significant

amount (column 7, lines 35-39). All of these characteristics disclosed by Krause et al '350 for the flexible region 16 are antithetical to a flexible region comprising a continuous helical cut.

The discussion in Krause et al '350 pertaining to the disadvantages of flexible regions comprising helical coils, which disadvantages the flexible region 16 is intended to overcome, further makes note of the fact that multiple helical coils are needed so that unwinding or expanding coils are counteracted by coils that wind or tighten in order to prevent the inner member from binding within the outer member (column 1, lines 48-53; column 2, lines 19-23).

The Examiner refers to Krause et al '922 as disclosing a continuous helical slot in a cutter tube from which it would have been obvious to use a continuous helical slot in the inner tube of Krause et al '350 instead of the many discontinuous slots 60,62. Applicant strongly disagrees with the Examiner. Krause et al '922 discloses a flexible shaft for transmitting torque from a rotatably driven end 14 to a driven part 15. There are no teachings or suggestions by Krause et al '922 that the flexible shaft 10 is rotatably disposed in an outer tubular member, much less conforming to a bend in an outer tubular member. Rather, Krause et al '922 discloses merely that the shaft has a high level of flexibility "to facilitate movement around, over or under an obstacle." Krause et al '922 illustrates a preferred use of the flexible shaft (Fig. 12) which clearly shows that the shaft is not rotatably disposed in an outer tubular member. Indeed, contrary to the flexible shaft being rotatably disposed in an outer tubular member, it is the intention of Krause et al '922 for the shaft itself to serve as an outer member that receives an inner member, i.e. guide wire or rod (Fig. 12).

From the teachings of Krause et al '350 and '922, it would not have been obvious to substitute the continuous helical slot in the flexible shaft of Krause et al '922 for the discontinuous slots 60,62 in the flexible region 16 of Krause et al '350. The flexible region 16 of Krause et al '350 involves an intentional departure from the structure and operational characteristics of helical cuts or coils that wind and unwind, and Krause et al '350 goes to great length in differentiating the flexible region 16 from helical cuts or coils. Krause et al '922 does not provide teachings applicable to a flexible inner member that is required to rotate within an outer tubular member and from which it would have been obvious to substitute the continuous helical slot of the flexible shaft 10 of Krause et al '922 for the discontinuous slots 60,62 of Krause et al '350, especially in light of the explicit teachings in Krause et al '350 that make it impossible to reasonably consider a helical cut or coil arrangement as an equivalent substitute for the slots 60,62. Moreover, the teachings in Krause et al '350 recognizing the need for multiple winding and unwinding helical coils to prevent binding of the inner member within the outer member further discourages a modification where the slots 60,62, which do not incur winding/unwinding, are replaced with a continuous helical cut.

The reasons stated by the Examiner in support of the obviousness of using the continuous helical slot of Krause et al '922 as a substitute for the slots 60,62 of Krause et al '350 are considered to be implausible. With respect to the first reason, that "it would simplify the manufacturing of the tube", there is no factual basis from which to conclude that the use of a continuous helical slot in the inner tube 14 of Krause et al '350 instead of the discontinuous slots 60,62 would simplify the manufacturing of the tube because Krause et al '350 actually discloses a process for forming the slots 60,62

in the inner tube 14 whereby flexible regions can be formed in several inner tubes at the same time (column 6, lines 36-42). With respect to the second reason, that it "would provide a mere alternative slot arrangement", the teachings of Krause et al '350 itself show that the slots 60,62 are not and are not intended to be a mere alternative or equivalent arrangement for a continuous helical coil or slot.

The Examiner relies further on Krause et al '922 as disclosing the use of a continuous elastomer tube 104 over a slotted tube, and acknowledges that the tube 104 is not disclosed as being a heat shrink tube. To rectify this deficiency, the Examiner relies on Cesarini et al (column 9, lines 47-53) for the teaching of a heat shrink tube to cover a slotted cutting tube in order to prevent tissue from getting caught in the slots. From there, the Examiner concludes it would have been obvious to place a heat shrink tube over the helical slotted inner cutting tube of Krause et al '350 as modified by Krause et al '922 in order to prevent tissue from getting caught in the slots, thus affecting the ability of the tube to bend properly, and in order to seal the lumen of the inner tube and prevent communication between the lumens of the inner and outer tubes. Applicant respectfully disagrees with the Examiner. Krause et al '350 discloses silicone rubber 124 disposed in each slot for the explicit purpose of avoiding clogging by reducing the tendency of tissue fragments to become caught on the edges of the slots as they pass through the inner tube (column 9, line 64 - column 10, line 1; column 10, line 64 - column 11, line 2), and the presence of silicone rubber 124 in each slot also prevents communication between the lumen of the inner tube and the lumen of the outer tube. Krause et al '350 explicitly discloses that the excess silicone rubber material that projects from the slots 126 beyond the outer or exterior surface 148 of the

inner tube 120 be removed, thusly restricting the silicone rubber 124 to be coextensive with the exterior surface 148 of the inner tube so that the silicone rubber does not interfere with the movement of the inner tube 120 within an outer tube (column 10, lines 35-52). Krause et al '350 thereby firmly establishes the undesirability of having any silicone rubber material, much less an actual sleeve structure, disposed over the outer surface of the inner tube and clearly leads away from modifying the inner tube 120 to include a tube or sleeve over the flexible region, much less for the very purpose already served by the silicone rubber material.

Furthermore, it should be noted that Krause et al '922 discloses an elastomer material, as opposed to an actual sleeve structure, and the tubular construction 104 is not the same as an actual structural sleeve but, rather, results only on account of the elastomer material being used to encapsulate the shaft (column 10, lines 58-67). As pointed out above, the flexible shaft of Krause et al '922 is used without an outer member or is itself the outer member for a guide wire, and the tubular construction 104 does not and cannot make it obvious to place a sleeve over the inner tube 14 of Krause et al '350, especially in light of the explicit teachings of Krause et al '350 regarding the undesirability of having any material or structure over the outer surface of the inner tube.

The disclosure in Cesarini et al (column 9, lines 47-53) relied on by the Examiner pertains to a shrink wrap tube to be placed over an outer tube to avoid material becoming lodged within slots in the bend region 18 of the outer tube and to help prevent the edges of the slots from causing damage. As with Krause et al '922, the shrink wrap tube of Cesarini et al does not and cannot make it obvious to place a

sleeve or tube over the inner tube of Krause et al '350. Moreover, as pointed out above, Krause et al '350 already discloses the use of silicone rubber 124, which is required to be coextensive with the outer surface of the inner tube, to prevent tissue from getting caught in the slots 60,62 and which also prevents communication between the lumens of the inner and outer tubes. There would be absolutely no reason to modify the inner tube of Krause et al '350 to include the elastomer material disclosed by Krause et al '922 or the shrink wrap tube of Cesarini et al for the purposes already served by the silicone rubber 124. Modifying the inner member of Krause et al '350 to include any kind of sleeve departs so clearly from the structure and objectives explicitly taught by Krause et al '350 that it cannot be considered obvious as asserted by the Examiner.

The Examiner relies on Whayne, Stephan et al and Hinohara et al as teaching use of an adhesive to set a heat shrink tube to the element it is covering, from which the Examiner improperly concludes that it would have been obvious to employ a coating of adhesive to secure a heat shrink tube over the flexible region 16 of Krause et al '350. Neither Whayne, Stephan et al nor Hinohara et al disclose or suggest a coating of adhesive disposed over an outer surface of an elongate tubular body, much less along a helically cut length portion thereof, with the adhesive bonding a heat shrunk sleeve to the outer surface of the body along the length portion as recited in independent claim 1. Whayne, it should be noted, discloses a covering 86 against a terminal end of a tubular formation 18 and not over an outer surface of a tubular body along a length portion thereof, and Whayne further refers to the adhesive being applied to edges of the shrink tubing (column 9, line 64 - column 10, line 17). Stephan et al discloses an adhesive for

bonding thermo-shrinking molded parts such as tubes ... against metal and against themselves (column 6, lines 22-29) and discloses a thermo-shrinking molded part such as cable coverings being coated internally only on both ends (column 8, lines 38-40). Hinohara et al discloses only that a polymeric tube 38 can be heat shrunk onto a core wire 32 with or without an additional adhesive. None of the references disclose or suggest a coating of adhesive disposed over an outer surface of an elongate tubular body along a helically cut length portion thereof with the adhesive bonding a heat shrunk sleeve to the outer surface along the length portion. On this basis alone it would not have been obvious to use a coating of adhesive to bond a sleeve over the inner tube of Krause et al '350 to arrive at the claimed invention. But moreover, as pointed out above, Krause et al '350 explicitly teaches away from having any material or structure over the outer surface of the inner tube, thusly teaching away from a modification that would place a coating of adhesive over the outer surface of the inner tube for the same reasons noted above that Krause et al '350 teaches away from placing a sleeve over the outer surface of the inner tube.

The heat shrunk sleeve bonded to the body of the inner member by the coating of adhesive along the helically cut length portion is required by independent claim 1 to provide resistance to wind-up and unwinding of the length portion of the body when transmitting torque which, according to additional recitations in claim 1, involves rotation in forward and reverse rotational directions. The Examiner states that Krause et al '350 discloses that the configuration of the inner tube resists winding and unwinding compared to a helical wire configuration, but what Krause et al '350 actually discloses is that winding and unwinding is not even an issue in the inner tube 14 because it is a

deliberate departure from a helical coil or cut configuration. It follows that there would be absolutely no reason whatsoever to modify Krause et al '350 to include a sleeve bonded to the body of the inner tube to provide resistance to wind-up and unwinding of the flexible region when transmitting torque in forward and reverse rotational directions because Krause et al '350 asserts the absence of wind-up and unwinding in the inner tube.

It is fundamental that a rejection based on Section 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. Ex parte Haymond, 41 USPQ 2d 1217 (Bd. of Pat. Appls. and Int. 1996). Obviousness of an invention cannot be established by combining the teachings of the prior art absent some teaching, suggestion or incentive supporting the combination. In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988). The motivation to combine references cannot come from the invention itself. In re Oetiker, 24 USPQ2d 1443 (Fed. Cir. 1992). The Examiner may not resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis. In re Warner, 154 USPQ 173 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968).

In the present case, the rejection of independent claim 1 is not supported by a factual basis. There are no teachings or suggestions whatsoever in Krause et al '350 and '922, Cesarini et al, Whayne, Stephan et al or Hinohara et al which would lead one to combine the teachings of the references to arrive at the claimed invention. In fact the objective teachings of Krause et al '350, the primary reference relied on by the Examiner, are contradictory to the claimed invention. The modification to Krause et al '350 asserted by the Examiner to be obvious based on the remaining references relied

on ignores the principal that consideration must be given to prior art which would lead one away from the invention. Mendenhall v. Aztec Industries, Inc., 13 USPQ2d 1913 (Dist. Ct., E.D. TN, 1988). It is not realistic to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. Ingersoll-Rand Co. v. Brunner & Lay, Inc., 474 F. 2d 491, 177 USPQ 112 (5th Cir. 1973), cert. denied, 414 U.S. 865, 179 USPQ 321 (1973). The only way the invention of claim 1 can be considered obvious in view of the references cited and applied by the Examiner is through improper hindsight reconstruction, made possible only through the teachings of the claimed invention itself and by using the claimed invention as a template to combine isolated random features of the prior art. Accordingly, independent claim 1 is submitted to be clearly patentable over Krause et al '350 in view of Krause et al '922, Cesarini et al and either Whayne, Stephan et al or Hinohara et al. It is submitted that independent claim 1 should be allowed along with its dependent claims 2-9.

Independent claim 10 recites "an elongate flexible inner tubular member ... comprising ... an elongate tubular body ... and a flexible region along said body ... comprising an outer wall along an outer diameter surface of said inner tubular member and an inner wall along an inner diameter surface of said inner tubular member, said outer wall being secured to said inner wall, said inner wall comprising a helically cut length portion of said body having a cut through the wall thickness of said body extending helically along said length portion, said outer wall comprising a continuous solid flexible surface covering said helically cut length portion, said flexible region conforming to said bend while

transmitting torque ... when said proximal end of said inner tubular member is rotated in forward and reverse rotational directions, said outer wall secured to said inner wall providing resistance to wind-up and unwinding of said helically cut length portion." A flexible inner tubular member having the features recited in independent claim 10 is not disclosed or suggested by Krause et al '350 in view of Krause et al '922 and Cesarini et al and either Whayne, Stephan et al or Hinohara et al for essentially the same reasons explained above in connection with independent claim 1.

Krause et al '350 goes to great effort to ensure that no material or structure is disposed over the outer surface of the slotted region of the inner tube, and Krause et al '350 clearly teaches away from an inner wall comprising a helically cut length portion of a tubular body and an outer wall secured to the inner wall. Krause et al '350 also teaches away from the concept of providing any type of material or structure over the slotted region of the inner tube to provide resistance to wind-up and unwinding because Krause et al '350 teaches that the conditions of wind-up and unwinding are not present in the inner tube. The remaining references relied on, Krause et al '922, Cesarini et al, Whayne, Stephan et al and Hinohara et al, fail to provide any teachings or suggestions that would have made it obvious to modify Krause et al '350 to arrive at the claimed invention. As with independent claim 1, the only way independent claim 10 can be considered obvious in view of the references relied on is through impermissible hindsight made possible from the teachings of the subject invention itself and by improperly using the subject invention as a template or guide to combine isolated random teachings of the references. Independent claim 10 is thusly submitted to be clearly patentable over Krause et al '350 in view of Krause et al '922 and Cesarini et al

and either Whayne, Stephan et al or Hinohara et al. Accordingly, independent claim 10 should be allowed along with its dependent claims 11-16.

In light of the foregoing, the subject patent application is submitted to be in condition for allowance with claims 1-16. Action in conformance therewith is courteously solicited. Should any issues in the subject application remain unresolved, the Examiner is encouraged to contact the undersigned attorney.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on September 14, 2007.

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